OCT 1 0 2001

510K(k) SUMMARY

SUBMITTER:	**Gambro Renal Products** **10810 West Collins Avenue** **Lakewood, CO 80215** **(303) 231-5075**
DATE PREPARED:	**March 19th, 2001**
DEVICE NAME:	**Gambro POLYFLUX 6L, 8L, and 10L Capillary Dialyzer/Filter Labeled for Single Use**
CLASSIFICATION NAMES:	**Hemodialyzer**
PREDICATE DEVICE:	**Gambro POLYFLUX 14S, 17S, & 21S**

Device Description:

Gambro POLYFLUX 6L, 8L, and 10L Capillary Dialyzers/Filters Labeled for Single Use

The Gambro POLYFLUX 6L, 8L, and 10L, Capillary Dialyzers/Filters labeled for single use are identical in design, materials, function and intended use to other Gambro POLYFLUX hemodialyzers which have been previously cleared by the FDA under a 510(k) Notification for single use (510(k) Notification K981414).

These devices are intended for use in hemodialysis for the treatment of acute and chronic renal failure and for certain types of intoxications. They may also be used in cases of acute fluid overload for the removal of plasma water. The membrane used in this device is polyarylethersulfone (PES) which is identical to the membrane utilized in the Gambro POLYFLUX 14S, 17S, 17R, 21S, and 21R, Hemodialyzers /filters labeled for single use which have been previously cleared for marketing in the United States under 510K Notifications (K982414). A copy of this clearance letter is included in Section XI. E of this Notification.

Blood enters a blood inlet port where it is distributed to the hollow fibers. Each hollow fiber has an inner diameter of approximately 215 microns (wet hollow fiber internal diameter) and a wall thickness of 50 microns. The number of hollow fibers in each hemodialyzer / filter is 10,00 for the POLYFLUX 6L, 10,000 for the POLYFLUX 8L, and 12,000 for the POLYFLUX 10L. This effective membrane length is 210 mm for the POLYFLUX 6L, and 250 mm for the POLYFLUX 8L and 10L. The effective membrane surface area is 1.4 square meters for the POLYFLUX 6L, 1.7 square meters for the 8L and 2.1 square meters for the 10L. The housing and end caps of this hemodialyzer / filter are made of polycarbonate. The fibers used in the Gambro POLYFLUX 6L, 8L, and 10L are of the same composition as those previously approved for the Gambro POLYFLUX

Hemodialyzers / Filters labeled for single use and multiple use (K982414). The patient's blood traverses the inside of the hollow fibers and exits the device via a blood exit port.

By means of a hydrostatic pressure or transmembrane pressure which is created by a combination of positive and negative pressures across the membrane, plasma water along with certain lower molecular weight solutes pass through the membrane and into the dialysate or filtrate compartment of the device. Removal of uremic toxins and waste products are removed from the patient's blood in this device by means of both diffusion and convection through the membrane and into the counter current flowing dialysis solution during hemodialysis. The dialysate exits the devices via a dialysate outlet port.

Predicate Devices:

DEVICE NAMES	Gambro POLYFLUX 14S, 17S, & 21S, Hemodialyzer / Filter
INTENDED USE	Hemodialyzer/Filter
510K NUMBER	K982414
APPROVAL DATE	3/26/99

With respect to performance, these hemodialyzer/filters perform in a manner substantially equivalent to each other. We therefore consider the proposed devices substantially equivalent to existing predicate devices in commercial distribution in the United States.

Intended Use:

POLYFLUX L Indications:

The capillary dialyzer is intended for use in hemodialysis and associated modalities for the treatment of chronic renal failure.

The size, weight, state of uremia, cardiac status and general physical condition of the patient must be evaluated by the prescribing physician before each treatment. ~~The choice of the appropriate dialyzer and associated equipment as well as the treatment operating parameters are the sole responsibility of the physician.~~

~~Special attention must be paid in connection with pediatric use.~~

These statements were deleted by a FAXed amendment on 10/10/01.

This indication statement is essentially the same as the indication statement for the predicate devices.

Technological Characteristics:

Comparing the proposed devices to the predicate devices, they are substantially equivalent to the predicate devices. Both the proposed and predicate devices use the same hollow fiber membrane and other blood and non-blood contact materials. Both the proposed and predicate devices use polycarbonate for the housing and header material and polyurethane for the membrane potting material and are steam sterilized.

Summary of Non-Clinical Tests:

In vitro performance testing was performed to establish and compare performance characteristics to the predicate devices.

Clinical Test Results:

No clinical testing was performed

Conclusions:

Testing performed on the Gambro POLYFLUX L Capillary Dialyzers/Filters indicates that they are safe, effective, and perform as well as the predicate devices, when used in accordance with the instructions for use. In vitro performance data and directions for use have been included in the labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2001

Jeffrey R. Shideman, Ph.D.
Director, Therapy Group Americas
Gambro Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K010985
Trade/Device Name: POLYFLUX 6L, 8L & 10L Capillary Dialyzer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: July 11, 2001
Received: July 12, 2001

Dear Dr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER (IF *KNOWN*): *Not yet assigned*

DEVICE NAME: Gambro Polyflux 6L, 8L, & 10L Capillary Dialyzer / Filter

INDICATIONS FOR USE: K010985

POLYFLUX L Indications:

The capillary dialyzer is intended for use in hemodialysis and associated modalities for the treatment of chronic renal failure.

The size, weight, state of uremia, cardiac status and general physical condition of the patient must be evaluated by the prescribing physician before each treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010985